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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,909	12/24/2003	Malcolm Wilson Moon	PC23548B	9163
22428	7590	06/03/2005	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			ANDERSON, REBECCA L	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/743,909	MOON ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 march 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 37-41 and 44-53 is/are pending in the application.
- 4a) Of the above claim(s) 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____  | 6) <input type="checkbox"/> Other: _____                                    |

*488*

### **DETAILED ACTION**

Claims 37-41 and 44-53 are currently pending in the instant application. Claims 37-41 and 44-46 are rejected and objected and claims 47-53 are withdrawn from consideration as being for non-elected subject matter.

### ***Election/Restrictions***

In applicant's remarks filed 23 March 2005, applicants' representative further traversed the restriction requirement on the basis that the examiner must fully search and examine a Markush-type generic claim according to MPEP 803.02. and that extending examination as urged would entail a consideration of only thirteen additional and discrete moieties for R3' and R4'. For essentially the same reasons as found in the previous office action, this argument is not found persuasive as the restriction requirement is made under 35 USC 121. 35 USC 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. So, here we have claims which involve more than one independent and distinct invention. Under 35 USC 121, the claims may be restricted and the examination limited to a restricted

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invention. While applicant argues that extending the examination would entail only thirteen additional and discrete moieties, it is noted that these moieties require a serious search burden as the search would require a multitude of various subclasses in classes 544, 546 and 548 and also a commercial database search which can be quite burdensome. T

**The elected invention for search and examination is therefore, still the products of the formula (I) wherein:**

**R3, R5, R6, R7, R4, R1', R8, R10 and R9 are as found in claim 37 and**

**R3' and R4' together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.**

The remaining subject matter of claims 37-41 and 44-46 that is not drawn to the above elected invention and the subject matter of claims 47-53 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example wherein R3' and R4' are lower alkyl optionally substituted hydroxy or R3' and R4' together with the nitrogen atom to which they are attached, form 2-(S)-hydroxymethylpyrrolidin-1-yl, 2-(S)-carboxy-pyrrolidin-1-yl, piperazin-1-yl, 4-methylpiperazin-1-yl, pyrro-1-yl, pyridin-1-yl, oxazol-3-yl, isoxazol-2-yl, pyrazin-1-yl, pyradizin-1-yl, quinolin-1-yl and imidazol-1-yl, etc.

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The above mentioned withdrawn compounds which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention, such as by pyridine, piperazine, oxazolyl, imidazolyl, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 544 subclass (358)+ piperazine, class 548 subclass (215)+ oxazolyl, class 548 subclass (356.1)+ imidazolyl, etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefor withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper and made FINAL.

***Response to Amendment and Remarks***

Applicants' amendment to the claims and the remarks filed 23 March 2005 have been considered. Applicants' amendment to the specification has overcome the objection to the specification.

Applicants' amendment to the claims has overcome the provisional obvious type double patenting rejection of the claims over 10/300,930.

While applicant has acknowledged the obvious type double patenting rejections over 10/429,895 and 10/774,415, defers a substantive response to each and requests the PTO to hold the rejections in abeyance until one or more of the cited applications has indicated allowable subject matter, it is noted that the provisional obvious type double patenting rejections over 10/429,895 and 10/774,415 are proper and are therefore maintained.

In regards to the obvious type double patenting rejection over US Patent No. 6451838 and US Patent No. 6710067, while applicant has amended the claims to include R9 as only  $-C(=O)NHR_{13}$  wherein R13 is lower alkyl substituted with amino or heteroalicyclic and optionally substituted with hydroxyl, the rejections are maintained. Applicant has stated that the instantly claimed subject matter is a narrow selection of the claimed genus in the '838 and '067 patents, that  $-C(=O)NHR_{13}$  is not one of the claimed substituents in the '838 and '067 patent and, therefore, the instantly claimed value for R9 cannot therefore be viewed as an obvious variant of the genus of substituents claimed in the '838 and '067 patents. However, this argument is not found persuasive as both the claims of the '838 patent and the '067 patent contain R9 as C-

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amido which is defined on column 10 of the '838 patent and column 9 of the '067 patent as a group  $-C(=O)NR^{13}R^{14}$ , for example diethylaminoethylaminocarbonyl, ethylaminoethylaminocarbonyl, 2-morpholinoethylaminocarbonyl, 3-morpholinopropylaminocarbonyl and 3-morpholino-2-hydroxypropylaminocarbonyl. Furthermore, preferences are found in the '838 and '067 patents for applicants' instantly claimed invention wherein  $R^9$  is  $C(=O)NHR^{13}$ . Therefore, the double patenting rejections of the claims over the '838 patent and the '067 patent are maintained.

#### ***Maintained Claim Objections***

Claims 37-41 and 44-46 are objected to as containing non-elected subject matter. Claims 37-41 and 44-46 presented drawn solely to the elected invention identified supra and free from the following double patenting rejections would appear allowable over the prior art of record.

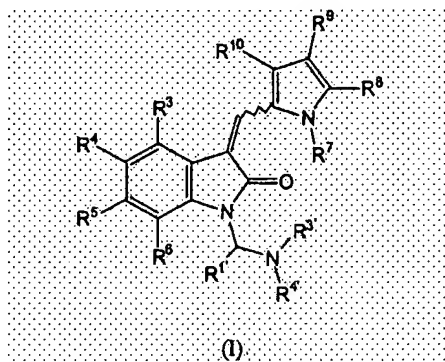
#### ***Maintained Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37-41 and 46 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6 and 8 of U.S. Patent No. 6451838. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected invention of Applicants instant claims 37-41 and 46 are drawn to pharmaceutical compositions and compounds of the formula (I):

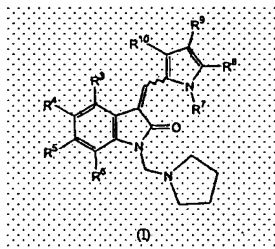


Wherein R<sup>3</sup>, R<sup>5</sup> and R<sup>6</sup> are for example, hydrogen, alkyl, trihaloalkyl, etc; R<sup>7</sup> is hydrogen, R<sup>4</sup> is hydrogen or halo, R<sup>1</sup> is hydrogen or methyl, R<sup>8</sup> and R<sup>10</sup> are independently unsubstituted lower alkyl, R<sup>9</sup> is =C(=O)NHR<sup>13</sup>, R<sup>13</sup> is lower alkyl substituted with amino or heteroalicyclic, R<sup>3</sup>' and R<sup>4</sup>', together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.



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The conflicting claims 1, 2, 4, 6 and 8 of US Patent No. 6451838 claims compounds of the formula (I):



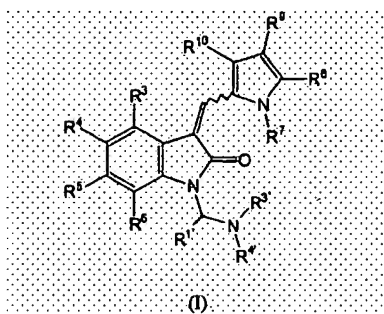
wherein the position equivalent to applicants R1' is hydrogen; the position equivalent to applicants R3' and R4' together with the nitrogen atom to which they are attached is an unsubstituted pyrrolidin-1-yl; conflicting R3, R4, R5 and R6 are for example, hydrogen, alkyl, trihaloalkyl, halo, etc.; conflicting R7 is, for example hydrogen and alkyl; conflicting R8 and R10 are for example, hydrogen or alkyl and conflicting R9 can be, for example, C-amido (conflicting claim 1). Conflicting claim 2 provided preferences to applicants instantly claimed compounds since conflicting claim 2 claims the compound of formula (I) wherein R7 is hydrogen. Conflicting claim 4 provides R8 and R10 as methyl.

Conflicting claim 6 is a pharmaceutical composition of the compound of conflicting claim 1. Therefore, claims 37-41 and 46 are rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over conflicting claims 1, 2, 4, 6 and 8 of US Patent No. 6451838 since the conflicting claims overlap with applicants instantly claimed invention and provide preferences towards applicants instantly claimed invention (see conflicting claims 2 and 4). Furthermore, column 10 of the specification defines C-amido as a group  $-C(=O)NR_{13}R_{14}$  and provides examples, such as, diethylaminoethylaminocarbonyl, ethylaminoethylaminocarbonyl, 2-morpholinoethylaminocarbonyl, 3-morpholinopropylaminocarbonyl and 3-morpholino-2-

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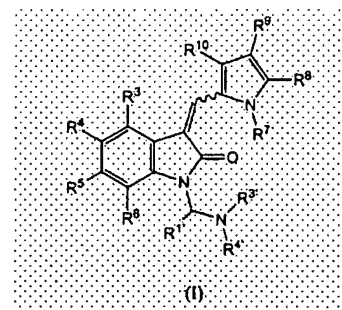
hydroxypropylaminocarbonyl and column 4 of the specification provides the most preferred R9 values to include 2-diethylaminoethylaminocarbonyl or 2-ethylaminoethylaminocarbonyl.

Claims 37-41 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 5-9 of U.S. Patent No. 6710067. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected invention of Applicants instant claims 37-41 and 46 are drawn to pharmaceutical compositions and compounds of the formula (I):



Wherein R<sub>3</sub>, R<sub>5</sub> and R<sub>6</sub> are for example, hydrogen, alkyl, trihaloalkyl, etc; R<sub>7</sub> is hydrogen, R<sub>4</sub> is hydrogen or halo, R<sub>1</sub>' is hydrogen or methyl, R<sub>8</sub> and R<sub>10</sub> are independently unsubstituted lower alkyl, R<sub>9</sub> is =C(=O)NHR<sub>13</sub>, R<sub>13</sub> is lower alkyl substituted with amino or heteroalicyclic, R<sub>3</sub>' and R<sub>4</sub>', together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.

Conflicting claims 1, 2 and 5-9 of US Patent No. 6710067 claim the pharmaceutical compositions and compounds of the formula (I)



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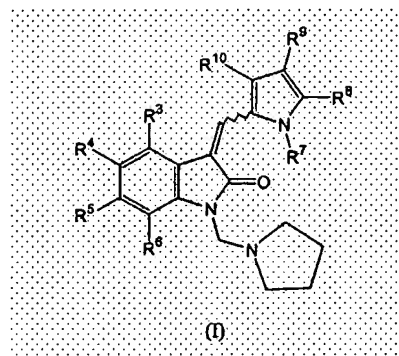
wherein the position equivalent to applicants R1' is hydrogen or alkyl; the position equivalent to applicants R3' and R4' together with the nitrogen atom to which they are attached is an unsubstituted pyrrolidin-1-yl; conflicting R3, R4, R5 and R6 are for example, hydrogen, alkyl, trihaloalkyl, halo, etc.; conflicting R7 is, for example hydrogen and alkyl; and conflicting R8 and R10 are for example, hydrogen and alkyl and conflicting claim 9 is, for example, C-amido (conflicting claim 1). Conflicting claim 2 provided preferences to applicants instantly claimed compounds since conflicting claim 2 claims the compound of formula (I) wherein R1' and R7 are hydrogen. Conflicting claim 5 has R3, R4, R5 and R6 as hydrogen and R8 and R10 as unsubstituted lower alkyl. Conflicting claims 6 and 7 provide a preference to R9 as C-amido. Conflicting claims 8 and 9 are pharmaceutical compositions claims comprising the compounds of the formula (I). Therefore, claims 37-41 and 46 are rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over conflicting claims 1, 2 and 5-9 of US Patent No. 671--67 since the conflicting claims overlap with applicants instantly claimed invention and provide preferences towards applicants instantly claimed invention. Furthermore, column 9 of the specification defines C-amido as a group  $-C(=O)NR_{13}R_{14}$  and provides examples, such as, diethylaminoethylaminocarbonyl, ethylaminoethylaminocarbonyl, 2-morpholinoethylaminocarbonyl, 3-morpholinopropylaminocarbonyl and 3-morpholino-2-hydroxypropylaminocarbonyl.

Claims 37-41 and 44-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25

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and 28-30 of copending Application No. 10/429895. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected invention of Applicants instant claims 37-41 and 46 are drawn to pharmaceutical compositions and compounds of the formula (I) wherein R3, R5 and R6 are for example, hydrogen, alkyl, trihaloalkyl, etc; R7 is hydrogen, R4 is hydrogen or halo, R1' is hydrogen or methyl, R8 and R10 are independently unsubstituted lower alkyl, R9 is -C(=O)NHR13, R13 is lower alkyl substituted with amino or heteroalicyclic, R3' and R4', together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.

Conflicting claims 22-25, 28, 29 and 30 are claiming pharmaceutical compositions and compounds of the formula (I)



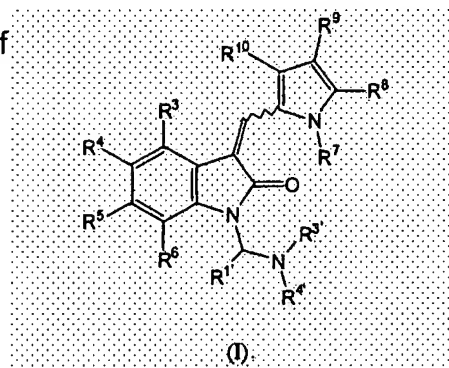
Wherein R3, R5 and R6 can be for example, hydrogen, alkyl, trihaloalkyl, etc; R7 is hydrogen, the position equivalent to applicants instant R1' is hydrogen, the position equivalent to applicants R3' and R4' along with the nitrogen to which they are attached is unsubstituted pyrrolidin-1-yl; R8 and R10 are unsubstituted lower alkyl and R9 is lower alkyl substituted with C-carboxy, or -C(=O)NHR13. Conflicting claim 28 provides R9 as 2-diethylaminoethylaminocarbonyl or 3-morpholin-4-yl-2-hydroxypropylaminocarbonyl, 2-ethylaminoethyl-aminocarbonyl and 3-morpholin-4-

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ylpropylaminocarbonyl which is a genus fully encompassed by applicants instantly claimed elected invention and therefore anticipates applicants instantly claimed elected invention.

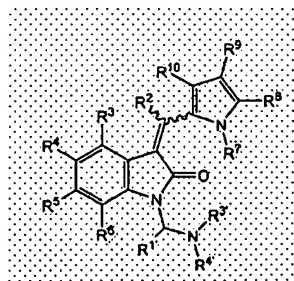
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37-41 and 44-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 60-62, 65, 66, 74-48 and 97-99 of copending Application No. 10/774415. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elected invention of Applicants instant claims 37-41 and 46 are drawn to pharmaceutical compositions and compounds of



Wherein R3, R5 and R6 are for example, hydrogen, alkyl, trihaloalkyl, etc; R7 is hydrogen, R4 is hydrogen or halo, R1' is hydrogen or methyl, R8 and R10 are independently unsubstituted lower alkyl, R9 is =C(=O)NHR13, R13 is lower alkyl substituted with amino or heteroalicyclic, R3' and R4', together with the nitrogen atom to which they are attached, form an unsubstituted pyrrolidin-1-yl.

Conflicting claims 60-62, 65, 66, 74-78 and 97-99 claim pharmaceutical compositions and compounds of the formula (II)



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Wherein R2 is hydrogen, R3, R4, R5, and R6 are for example, hydrogen, alkyl, trihaloalkyl, halo; R7 is for example, hydrogen or alkyl, R8 and R10 are unsubstituted lower alkyl, R1' is hydrogen or alky (conflicting claim 60), R9 is preferably (2-diethylaminoethyl)aminocarbonyl or (2-ethylaminoethyl)-aminocarbonyl (conflicting claims 61 and 62); R3' and R4' preferably form a pyrrolidin-1-yl (conflicting claims 65 and 66). Conflicting claims 74-77 provide preferences towards applicants instantly claimed invention since R1', R3, R5, R6 and R7 are hydrogen, R4 is halo, R8 and R10 are unsubstituted lower alkyl, R9 can be (2-diethylaminoethyl)aminocarbonyl (conflicting claims 75 and 76 and R3' and R4' form a pyrrolidin-1-yl group (conflicting claim 77). Furthermore, conflicting claim 78 claims, for example, a compound (3Z)-3-[[3,5-dimethyl-4-(2-diethylaminoethylaminocarbonyl)-1H-pyrrol-2-yl]-methylidene]-1-(1-pyrrolidinylmethyl)-1,3-dihydro-2H-indol-2-one which provides further preference towards applicants instantly claimed compound. Claims 97-99 are pharmaceutical composition claims. Therefore, claims 37-41 and 43-46 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over conflicting claims 60-62, 65, 66, 74-78 and 97-99 since the conflicting claims overlap with applicants instantly claimed invention, provide preferences towards applicants instantly claimed invention and provide the compound (3Z)-3-[[3,5-dimethyl-4-(2-diethylaminoethylaminocarbonyl)-1H-pyrrol-2-yl]-methylidene]-1-(1-pyrrolidinylmethyl)-1,3-dihydro-2H-indol-2-one which is completely encompassed by applicants instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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5/3/06



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